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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,056

09/22/2003

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1001.1708101

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11050 7590 08/02/2011
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EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

08/02/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/667,056
Filing Date: September 22, 2003
Appellant(s): MCFERRAN, SEAN

Sean McFerran
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/9/2011 appealing from the Office action mailed 10/13/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 13 and 15-28 are pending.

Claims 13 and 15-17 and 21-28 are rejected.

Claims 18-20 have been indicated as allowable.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

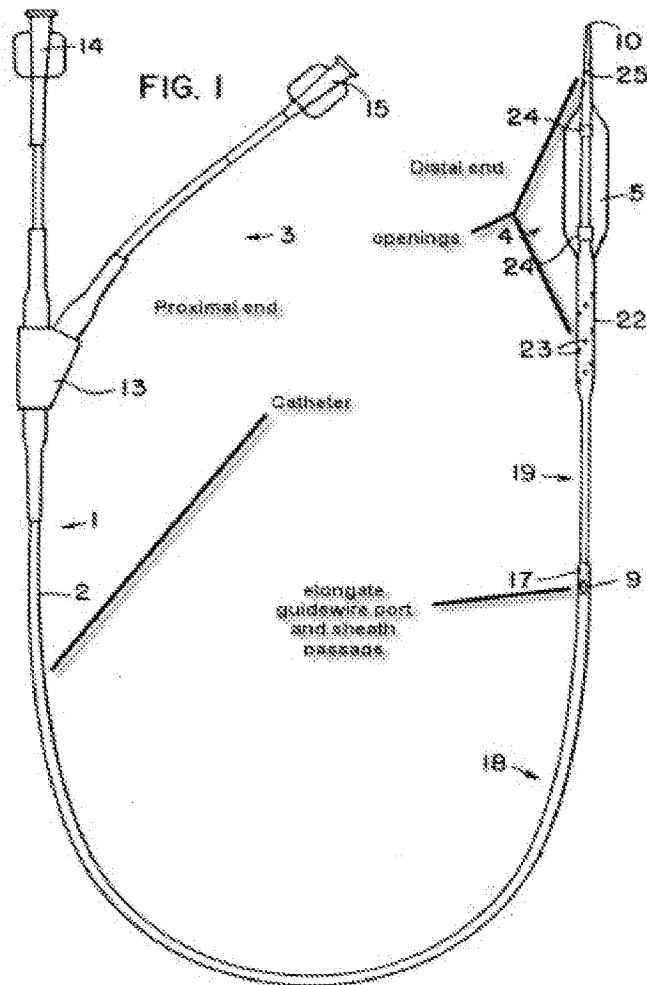
The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,306,247	Pfenninger	4-1994
6,346,093	Allman, et al.	2-2002

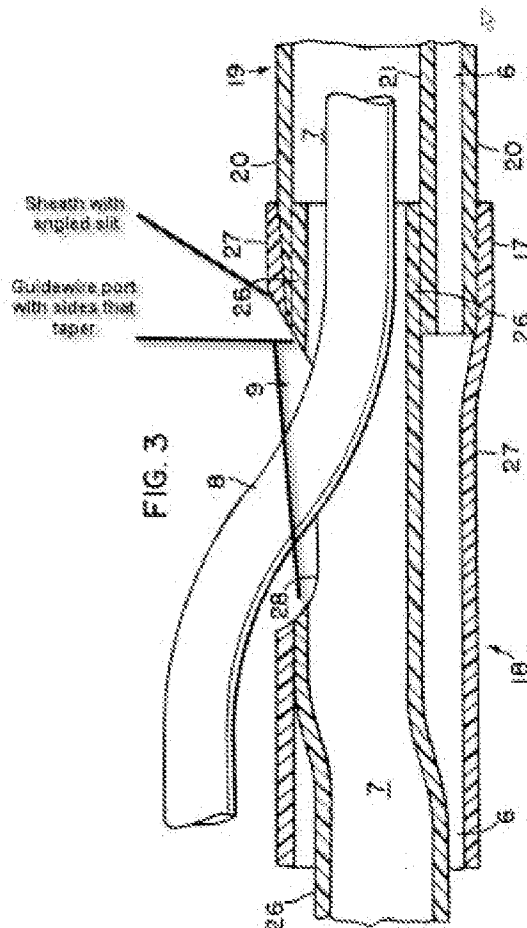
(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:



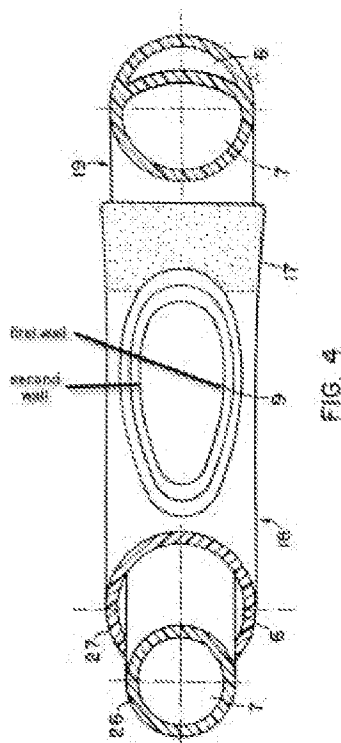
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Further note the Sheath (27), angled slit see figure below, guidewire port (near 9 or 28) with tapered walls (see marked up figure 3 below).



Concerning claim 15-16, see near 27 in figure 3.

Concerning claim 23 see marked up figure 4 below. Concerning claim 24 note slit length is larger then port length. Concerning claim 25-26 note port near 28 tapered edges as in figures 3 and 4.



Pfenninger discloses the claimed invention except for the longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided. Allman teaches that it is known to use a longitudinal angled slit configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided as set forth in paragraphs at column 8 lines 1-46 also see slit 118 in figure 4 and 4b or near 134 in figure 4c to provide and allow a guidewire to be radially slid into or out of the sheath assembly. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Pfenninger with a longitudinal angled slit as taught by Allman, since such a modification would

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provide the system with a longitudinal slit for providing and allowing a guidewire to be radially slid into or out of the sheath assembly.

Concerning claim 21 and 22, Pfenninger discloses the claimed invention except for the length of the guide wire port is at least six times greater than the width. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the guidewire port have a length six times greater than the width, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Concerning claims 21-28 see response to applicants arguments above. Concerning the claim language of "wherein when no guidewire is provided through the passage, the single lumen is substantially fluid tight from the proximal end of the elongate shaft to the opening at the distal end of the elongate shaft" see response to arguments above.

(10) Response to Argument

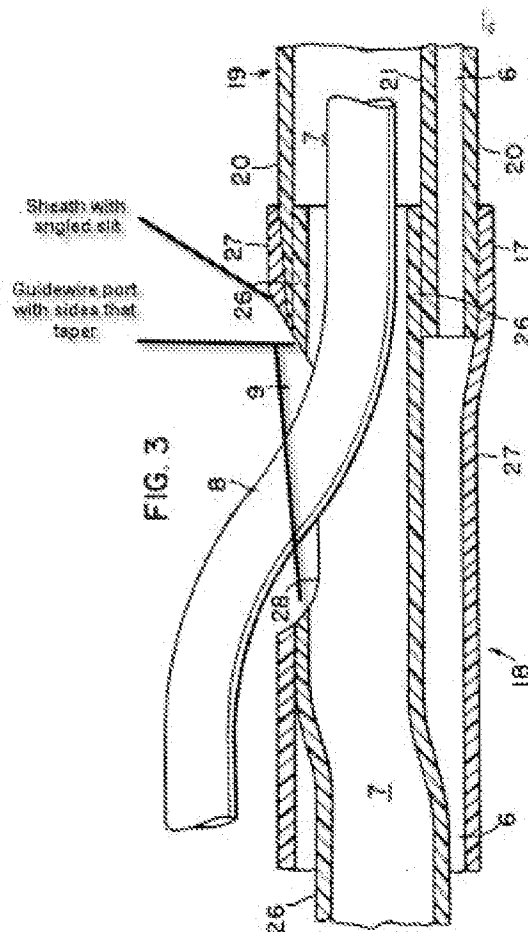
Appellant's first argument is directed towards the 35 U.S.C. 103(a) rejection over Pfenninger (U.S. Patent 5,306,247) in view of Allman et al. (U.S. Patent 6,346,093). Appellant's argue that Pffenninger nor Allman, when taken alone or in combination teach "the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath, the slit disposed parallel to a

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longitudinal axis of the elongate shaft", among other limitations (see page 9 of appeal brief). Examiner disagrees and is of the position that the combination of Pfenninger in view of Allman does disclose the claim limitations associated with the angled slit, its depth, and disposition along the longitudinal axis of the elongate shaft.

Again examiner draws attention to the marked up figure of Pfenninger to teach "the polymer sheath including a passage comprising an angled slit extending radially through the polymer sheath at an angle such that the slit has a depth that is greater than a thickness of the polymer sheath..."

Note the Sheath (27), angled slit see figure below (cut out portion from element 27, guidewire port (near 9 or 28) with tapered walls (see marked up figure 3 below).

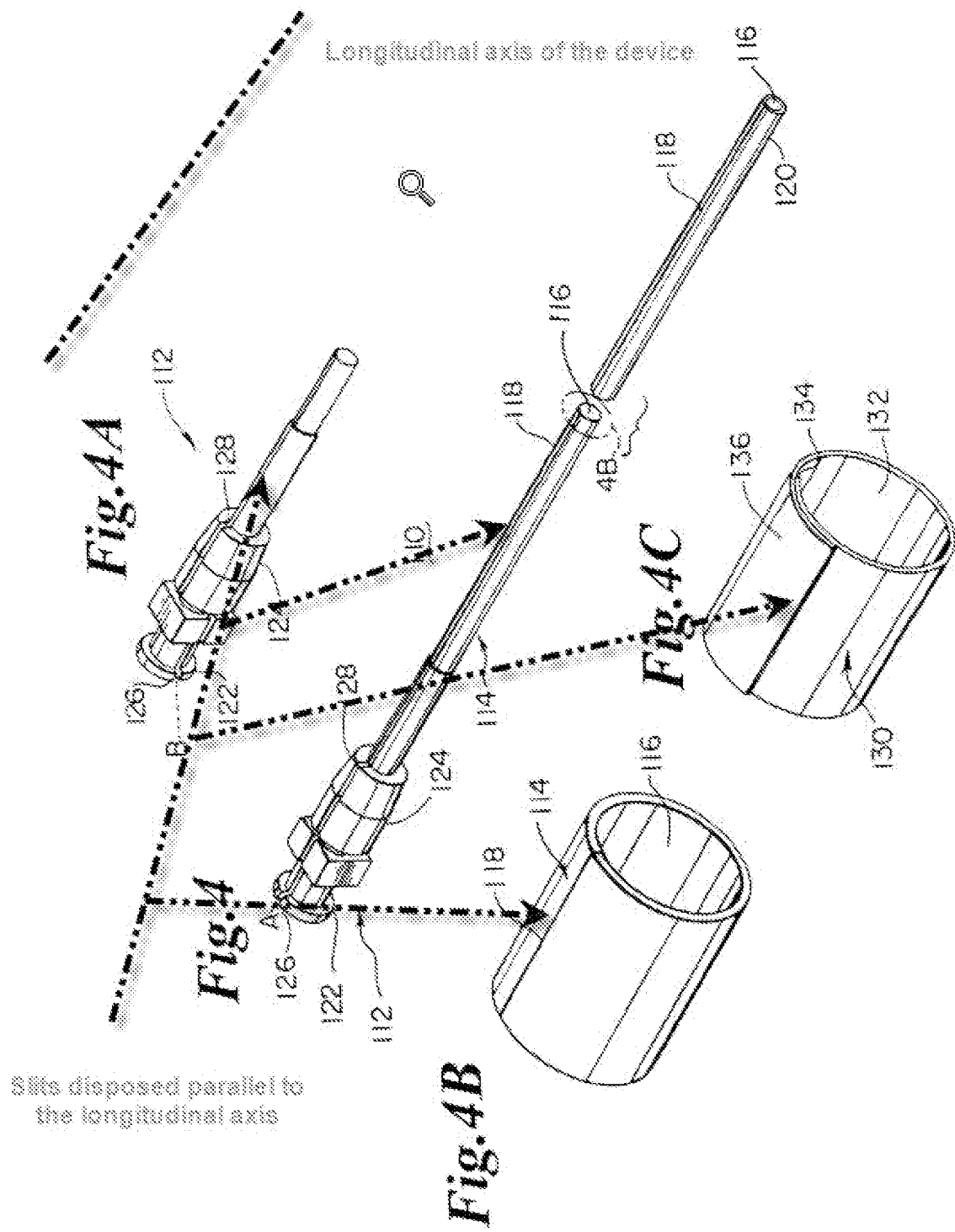


It is examiners position that the angled cut out portion from sheath 27 is the "slit" (labeled above) and this slit has a length which is greater than the thickness of the sheath 27 (angled portion length is greater than the thickness of the sheath since angled slit forms the hypotenuse and the thickness of the sheath is one side of a common triangle. It is examiners position that the angled wall portion or cut away portion from sheath 27 would be considered a "slit" since it is a long narrow cut or opening (as defined in appellant's remarks page 13), since it is a long entry way cut from the sheath 27 to permit entry into the pathway of the sheath.

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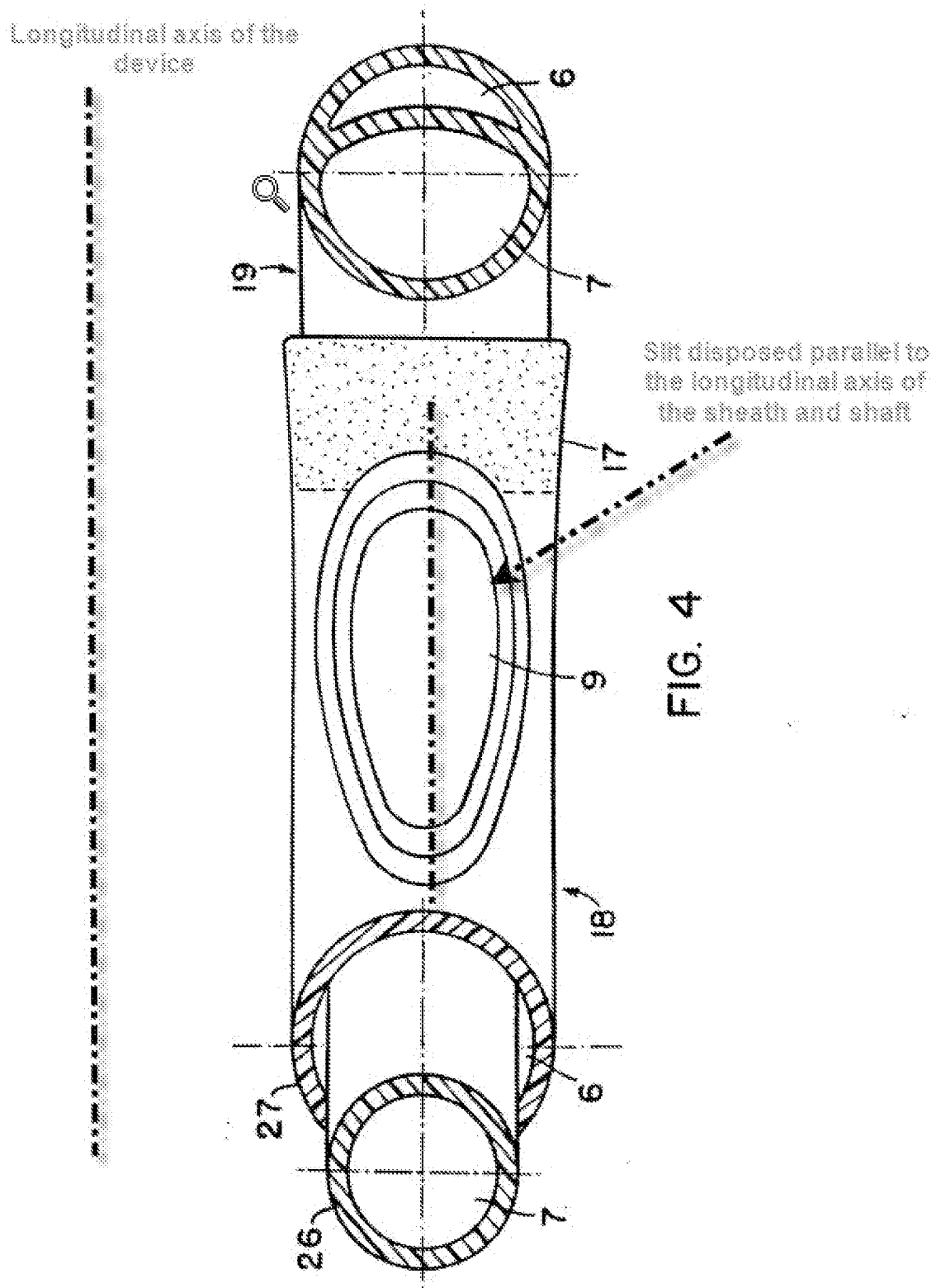
Appellants further argue that Pfenninger's nor Allman's "slit" extends parallel to a longitudinal axis of the elongate shaft. Examiner disagrees. It is Examiner's position that both Pfenninger and Allman disclose and teach an angled slit whose measured length is parallel to the length of the sheath and parallel to the length of the shaft.

See Allman marked up figures below for Slits parallel to the shaft and sheath.



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See Pfenninger marked up figures below for Slits parallel to the shaft and sheath.



With these disclosures of Allman and Pfenninger it is examiners position that the slit has a greater length than the thickness of the sheath and the slit has a length that is parallel to the shaft and parallel to the longitudinal axis of the sheath.

Appellant's next argument is that Pfenninger and Allman fail to disclose a slit that extends along only a portion of the length of the sheath (Appeal Brief Page 14). Examiner disagrees and points out figures 3 and 4 of Pfenninger above which shows that the slit (near 9 cut from sheath 27 extends only partway and not the entirety of sheath 27/18 (as in figures 3 and 4 of Pfenninger).

Appellant's next argument is towards the combination of the prior art Pfenninger in view of Allman. Appellants argue that there is no articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Further there already is an opening in Pfenninger so one would not modify Pfenninger since the size and shape have particular advantages (Appeal brief page 14), and the combination would change the principle operation of the device of Pfenninger (appeal brief page 15). Examiner disagrees.

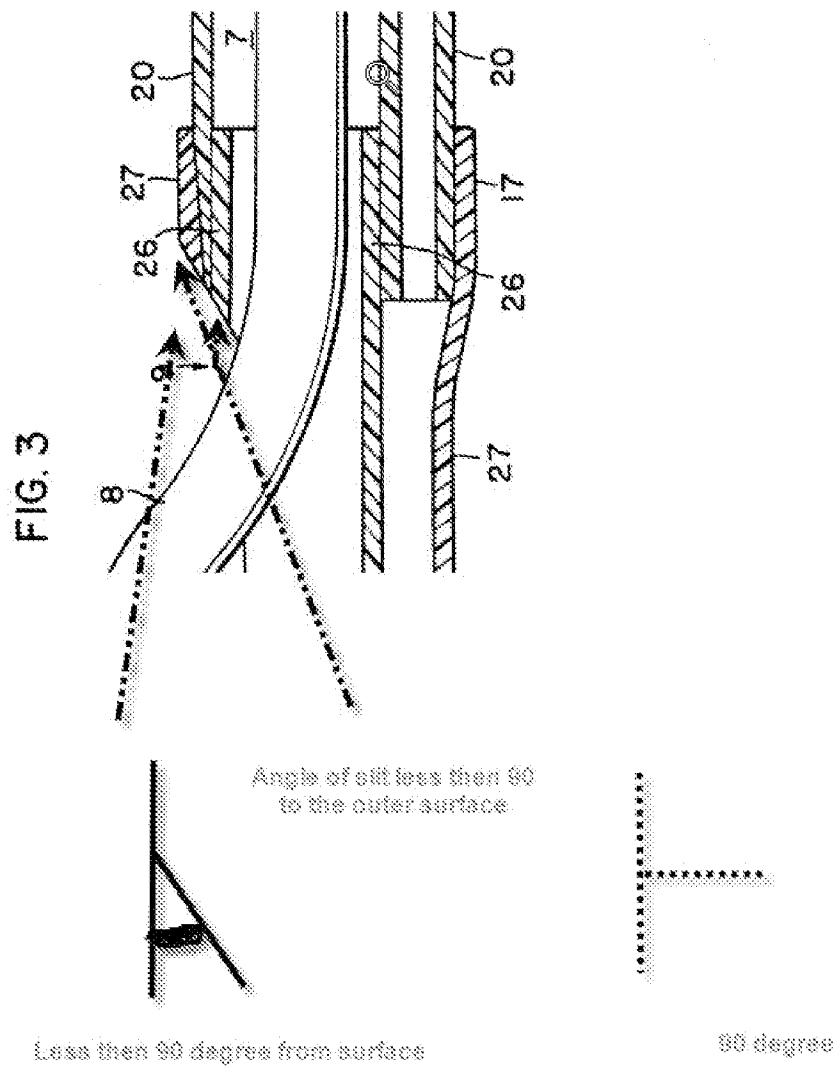
It is examiners position that the combination of Pfenninger in view of Allman would disclose the appellants claimed invention and further this combination would not change the principle operation of the device. It is examiners position that Pfenninger discloses the claimed invention except for the longitudinal angled slit **configured to permit guidewire access through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided**. Allman teaches that it is known to use a longitudinal angled slit configured to permit guidewire access

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through the guidewire port while maintaining a substantially fluid tight in use when no guide wire is provided as set forth in paragraphs at column 8 lines 1-46 also see slit 118 in figure 4 and 4b or near 134 in figure 4c to provide and allow a guidewire to be radially slid into or out of the sheath assembly. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Pfenninger with a longitudinal angled slit as taught by Allman, since such a modification would provide the system with a longitudinal slit for providing and allowing a guidewire to be radially slid into or out of the sheath assembly.

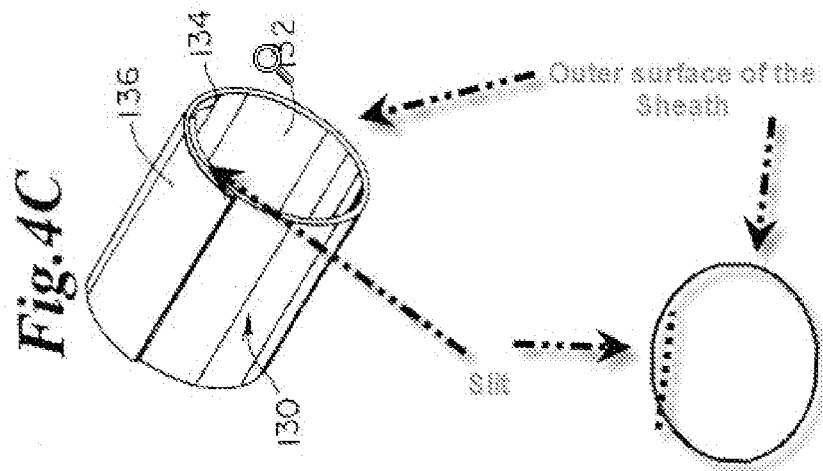
In this prior art combination the principle operation of provided fluid is still carried out as well as guidewire entry into the shaft passageway. The fluid tight feature would be an additional obvious modification and advantage in order to insert guidewires to be radially slid into or out of the sheath assembly in a controlled and fluid tight manner. Therefore examiners disagrees with the appellants positon that the combination of the prior art references would change the principle operation or destroy the references.

Appellant's next argument is directed to Allman failing to teach an angle less then 90 degrees to the outer surface of the polymer sheath. It is examiners position that Allman and Pfenninger both does disclose this claim limitation. See marked up figure of Pfenninger with an angle less then 90 degrees to the outer surface of the polymer sheath.



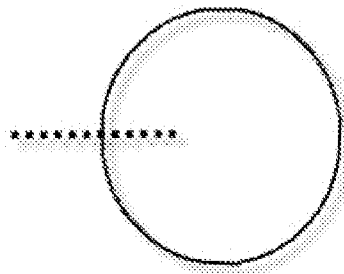
See marked up figure of Allman with an angle less than 90 degrees to the outer surface of the polymer sheath.

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Slit extends at an angle less than 90 degrees from the outer surface of the sheath

Not at a 90 degree angle

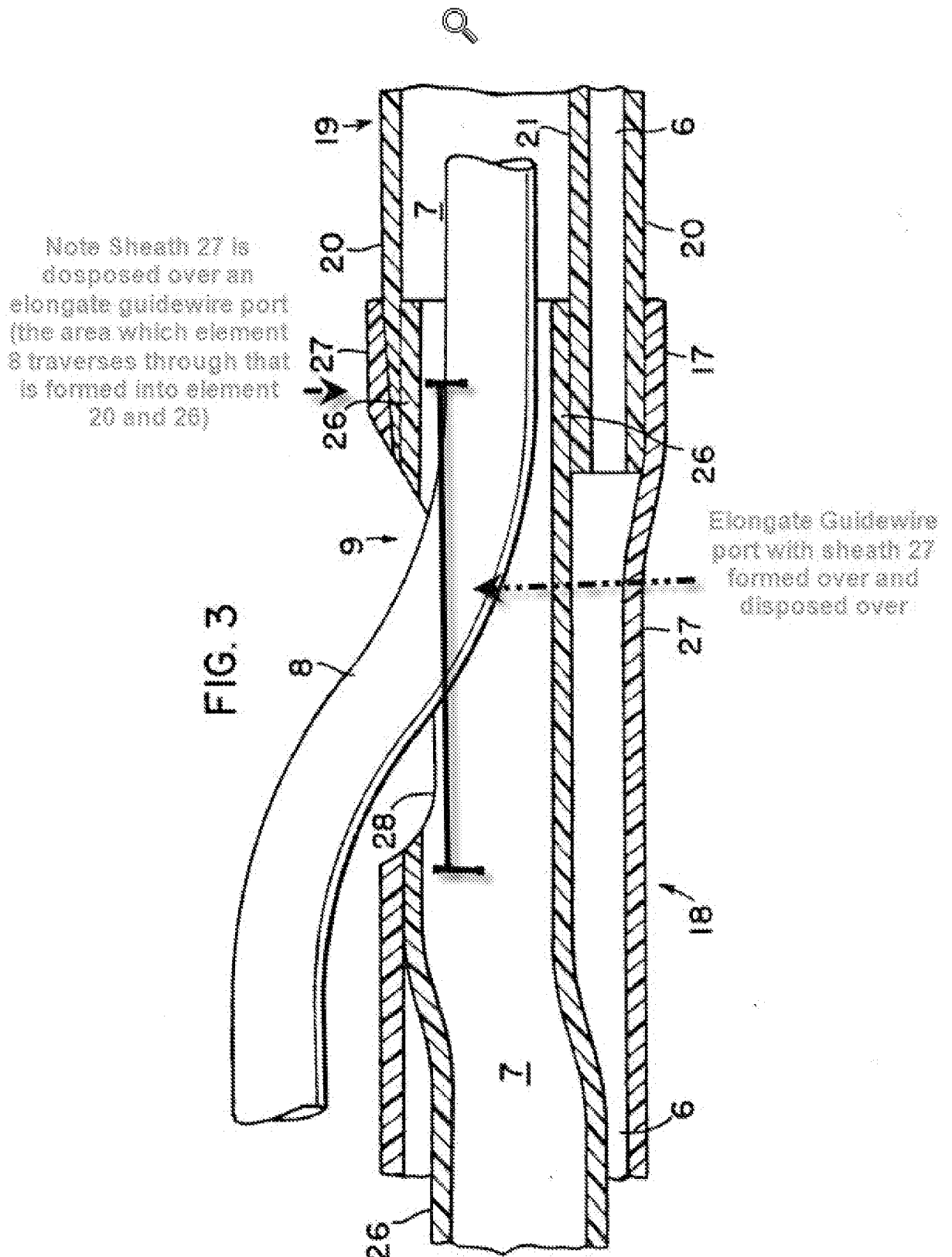


It is examiner's position that both Pfenninger and Allman each teach the slit having an angle which is less than 90 degrees from the outer surface of the sheath.

Appellant's next argument is directed to claim 17 and that Allman or Pfenninger fails to teach or suggest "an angled slit is configured to accept both a guidewire and a sheath wherein the sheath is configured to accept the guidewire therein" (appeal brief page 16). Examiner is of the position that Pfenninger in figure 3 discloses the ability that the slit is "configured" to accept both a guidewire (see element 8) and a sheath, and the sheath is "configured" to accept the guidewire therein (see element 8 in pathway of sheath 27). Further Examiner is of the position that Allman slit is also configured for the guidewire accepted in the slit and accepted in the sheath. See Allman figure 1 and 5 and guidewire element 36 entering the slit and the sheath. Therefore it is examiners position that both of the prior art references disclose that this guidewire is accepted in the slit and the sheath (as in claim 17 for example).

Appellants next argue that independent claim 27 is not disclosed in the prior art Pfenninger in view of Allman. Particularly Appellants argue that ... "a polymer sheath disposed over the elongate guidewire port" is not shown in Pfenninger (Appeal Brief page 19). Examiner disagrees.

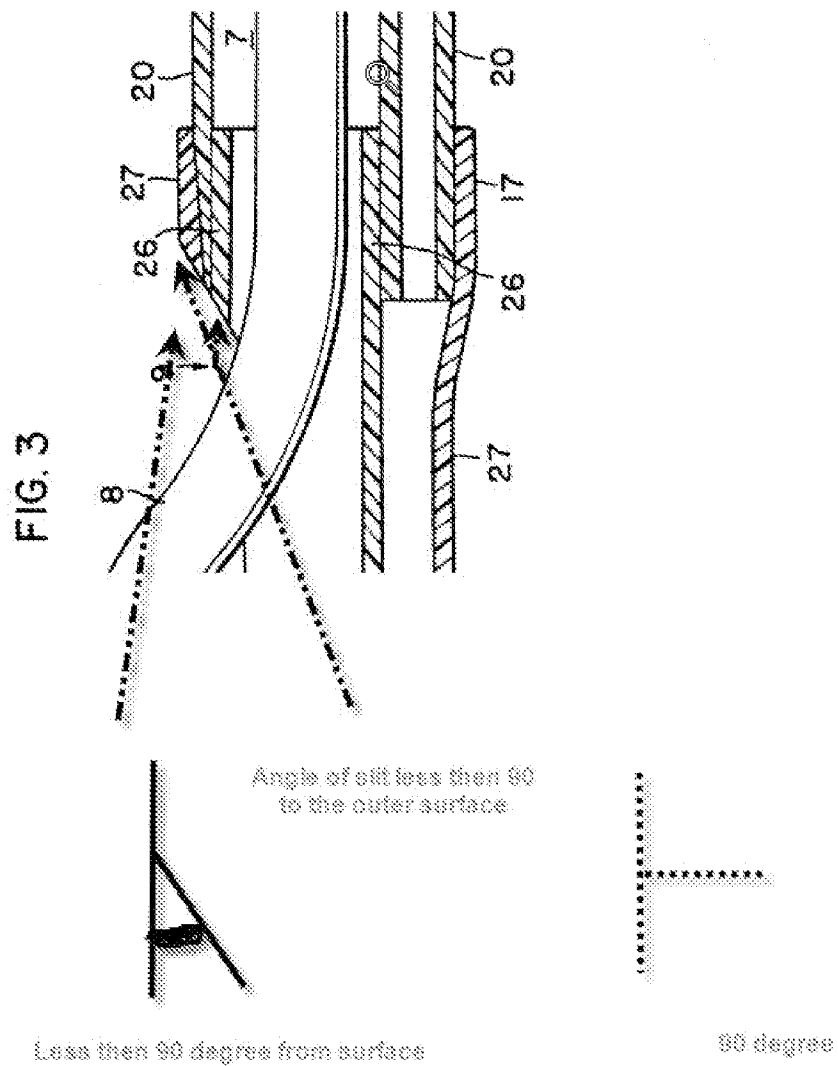
It is examiners position that Sheath 27 is formed over the guidewire port, which is further formed in underlying layers of the Pfenninger device. See marked up figure below.



Again appellants argue that the Examiner has failed to disclose a "slit". Examiner is of the position that the cut into 27 is a slit in Pfenninger and Allman see marked up figure 4c (provided above), further see remarks above addressing this "slit" element in the preceding remarks.

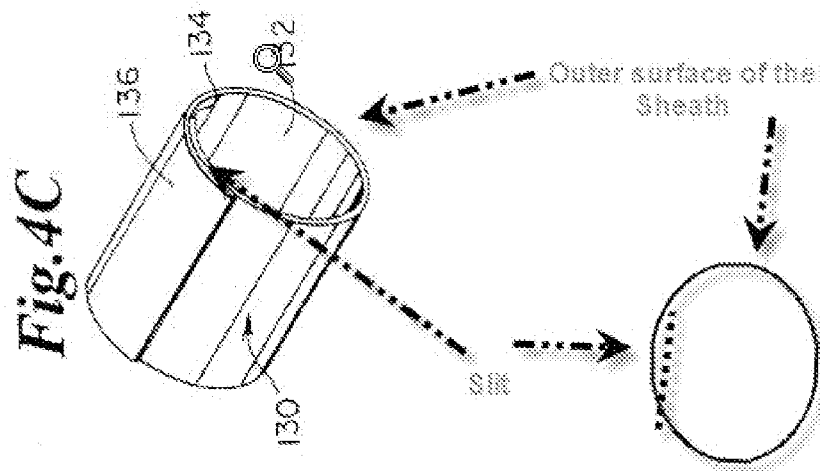
Appellants further argue each of the points in independant claim 27, as they argued in claim 1, the prior art fails to disclose a slit, the slit is not angled with a length greater then the thickness of the sheath wall, the angle is not less then 90 degrees, there is not articulated reasoning with some rational underpinning for the combination of Pfenninger in view of Allman, and the combination of the references would change the principle operation of the device of Pfenninger. Again examiner disagrees and takes the opposite position on each of those points. Examiner reiterates the response to those arguments (as in claim 1) as previously stated above. Further appellants argue that concerning claim 28 a slit extending radially through a polymer sheath at an angle less then 90 degrees is not shown in the prior art.

Again, it is examiners position that Allman and Pfenninger both does disclose this claim limitation. See marked up figure of Pfenninger with an angle less then 90 degrees to the outer surface of the polymer sheath.



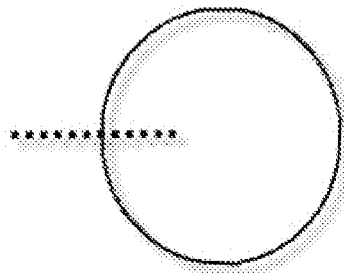
See marked up figure of Allman with an angle less than 90 degrees to the outer surface of the polymer sheath.

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Slit extends at an angle less than 90 degrees from the outer surface of the sheath

Not at a 90 degree angle



It is examiner's position that both Pfenninger and Allman each teach the slit having an angle which is less than 90 degrees from the outer surface of the sheath.

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It is Examiner's position that the elements disclosed in Pfenninger in view of Allman are fully capable of satisfying all structural, functional, spatial, and operational limitations in the claims, as currently written, and the rejection is made and proper.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Phillip Gray/

Examiner, Art Unit 3767

Conferees:

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767

/Michael Phillips/

RQAS